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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/936,514 | 09/14/2001 | Takeya Abe | 018793-253 | 4410 |
| 7590 | | 10/11/2006 | EXAMINER | |
| Robert G Mukai Burns Doane Swecker & Mathis PO Box 1404 Alexandria, VA 22313-1404 | | | FRONDA, CHRISTIAN L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,514

Applicant(s)

ABE ET AL.

Examiner

Christian L. Fronda

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,11-16 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,11-16 and 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2005 has been entered.
2. Claims 1, 3, 9, 11-16, and 25-31 are pending and under consideration in this Office Action.
3. The previous objection to claims 9-16 because the claims depend from cancelled claims 7 and 8 has been withdrawn in view of applicants' amendment to the claims filed 10/19/2005.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 1, 3, 9, 11-16, and 25-31 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The arguments filed 10/19/2005 have been fully considered but they are not persuasive for the reasons of record as supplemented below.
Claims as amended are still genus claims directed toward a method using a genus of nitrile hydratase of any amino acid sequence and structure from any microorganism fungus body although the claims have been amended to include the limitation "for removing a protein". The scope of the claims includes many microorganisms and many nitrile hydratase enzymes with widely differing structural, chemical, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

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As stated in the previous Office Action recitation of the name "nitrile hydratase" and its source as a microorganism fungus body do not define any structural features and amino acid sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features and amino acid sequences commonly possessed by the genus. As stated in the previous Office Action, the specification discloses a MT-10827 (FERM BP-5785) which is not a not a fungus, but is instead an *E.coli* host cell transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352), and its use in converting acylonitrile to its corresponding amide acrylamide.

However, the specification does not provide an amino acid sequence of the said bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095, and fails to provide a written description of additional nitrile hydratase enzymes and microorganisms as encompassed by the claimed genus in the amended claims. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the claimed genus.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of nitrile hydratase of any amino acid sequence and structure from any microorganism fungus body

Amending the claims to recite the *E.coli* host cell MT-10827 (FERM BP-5785) transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352) may overcome the rejection.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3, 9, 11-16, 25-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oriel et al. (WO 99/55719; reference of record) in view of Chen. (J Biol Chem. 1967 Jan 25;242(2):173-81; reference of record). The reference teachings have been stated in the previous Office Actions. Applicants' arguments filed 10/19/2005 have been fully considered but they are not persuasive.

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One of ordinary skill in the art at the time the invention was made would have been motivated to modify the process of Oriel et al. such that the amide solution is subjected to acid-charcoal treatment as taught by Chen as stated in the previous Office Actions for the purposes of having a simple and beneficial purification process that produces an amide compound and removes impurities. The examiner takes the position that the modified process of Oriel et al. would inherently remove impurities including proteins since the process involves not only contacting the solution with activated carbon but also includes steps for concentrating or precipitating by distillation or evaporation the amide solution, thereby removing contaminating proteins.

The examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the amended claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

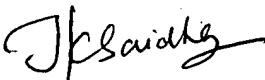
Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER